Individual Safety Report

3499283-2-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

McNeil Consumer Healthcare
McNeil Consumer Healthcare
Fort Washington, PA 19034-2299

Page ____ of ____

Approved by FDA on 11/15/93

Mfr report #

UF/Dist report #

FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] In confidence	68 yrs or Date of birth:	(X) female ( ) male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- ( ) death (mo/day/yr)
- ( ) life-threatening
- ( ) hospitalization - initial or prolonged
- ( ) disability
- ( ) congenital anomaly
- (X) required intervention to prevent permanent impairment/damage
- ( ) other:

3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)
3/8/00	05/01/00

5. Describe event or problem

Consumer alleges that the use of Extra Strength TYLENOL® acetaminophen Caplets was associated with LIVER FUNCTION TESTS ABNORMAL (liver function out of kilter), HYPOCHROMIC ANEMIA (hemoglobin 13.7, then 12, down to 11 in 2 yrs time) and SEDIMENTATION RATE INCREASED (sed rate high). Consumer reports using 500 mg of Extra Strenth TYLENOL, two to three times daily for approximately 3 years for fibromyalgia. According to consumer, approximately 2 years ago, her hemoglobin was 13.7. Approximately 1 year ago, her hemoglobin reportedly decreased to 12. Consumer also reports experiencing "sharp pains in the top of her head" (HEADACHE) upon awakening. On 3/8/00, consumer went to her rheumatologist who reportedly diagnosed her headaces as temporal ARTERITIS & prescribed prednisone. Physician also reportedly took blood tests & found that her hemoglobin had decreased further to 11, her "sed rate was 68" and "liver function out of kilter". According to consumer, her rheumatologist does not feel these (See Sect B7)

6. Relevant tests/laboratory data, including dates

approximately 3/98: hemoglobin was reportedly 13.7; approximately 3/99: hemoglobin was reportedly 12; 3/08/00: hemoglobin was reportedly 11, sed rate reportedly 68 and "liver function out of kilter"

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

hypothyroidism, fibromyalgia; allergic to penicillin, sulfa medications, ZITHROMAX®

(Sect B5 cont) symptoms are related to TYLENOL use and reportedly did not prescribe any further treatment.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Extra Strength TYLENOL Caplets

#2

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 500 mg, bid-tid, po	#1 4/97-continuing;approx 3 yrs
#2	#2

4. Diagnosis for use (indication)

#1 fibromyalgia

#2

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)	7. Exp. date (if known)
#1 CJA074	#1 07/31/03
#2	#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

SYNTHROID®

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Healthcare
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

MAY 12 2000 DSS

2. Phone number

215-273-7303

3. Report source (check all that apply)

- ( ) foreign
- ( ) study
- ( ) literature
- (x) consumer
- ( ) health professional
- ( ) user facility
- ( ) company representative
- ( ) distributor
- ( ) other:

4. Date received by manufacturer (mo/day/yr)

05/01/00

5.

(A) NDA # 19-872

IND #

PLA #

pre-1938 ( ) Yes

OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

- ( ) 5-day (X) 15-day
- ( ) 10-day ( ) periodic
- (X) Initial ( ) follow-up #

8. Adverse event term(s)

LIVER FUNC ABNO ANEMIA HYPOCHRO
ESR INC HEADACHE
ARTERITIS

MAY 11 2000

9. Mfr. report number

1355159A

E. Initial reporter

1. Name, address & phone #

FDA MAY 11 2000 CDER EVALUATION AND RESEARCH

2. Health professional?	3. Occupation	4. Initial reporter also report to FDA
( ) Yes ( ) No		( ) Yes ( ) No ( ) Unk

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.